DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94834d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER
NWE-26-04W

June 10, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John C. Reynolds
54 Woods Hill Road
Swanton, VT 05488

Dear Mr. Reynolds:

A tissue report received by the U.S. Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in a cow that originated from your dairy farm. An inspection of your dairy farm located at 54 Woods Hill Road, Swanton, VT that was conducted by Food and Drug investigators on May 11-13, 2004 as a follow-up to this reported residue confirmed that you offered a dairy cow for sale for slaughter as human food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

You also caused an animal drug to become adulterated because the drug was used in a manner that does not conform to its approved uses or the extralabel use regulations in Title 21, Code of Federal Regulations, part 530 (21 CFR Part 530). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act. You can find the Act and associated regulations on the Internet through links on FDA's web page www.fda.gov.

On or about November 11, 2003, you treated a dairy cow on your farm identified with back tag No. 131Z4726 with Sulfadimethoxine. On November 12, 2003, your dairy cow, identified by back tag # 131Z4726, was transported by [redacted] cattle dealer, to [redacted] for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of Sulfadimethoxine in the animal's muscle tissue at a level of 3.40 ppm. The established tolerance for Sulfadimethoxine in cattle is 0.1 ppm (21 CFR 556.640). The presence of Sulfadimethoxine in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under section 402(a)(2)(C)(ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of section 512. Likewise, a food is adulterated under Section

402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals, which are ultimately offered for sale for slaughter as food, under conditions that may allow medicated animals bearing possibly harmful drug residue to enter the food supply.

For example, our investigators noted the following conditions on your farm:

1. You lack an adequate record keeping system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate record system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows.

4. You lack an adequate system to assure that expired drugs are discarded and not used.

The investigation also determined that you adulterated the animal drug Sulfadimethoxine which was indicated as the cause of your illegal tissue residue, within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling or the extralabel use regulations at 21 CFR part 530. Your use of the drug contrary to the directions and without following labeled withdrawal periods causes the drug to be unsafe under Section 512(a) of the Act and adulterated with the meaning of Section 501(a)(5) of the Act.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for human consumption, you are responsible for assuring that your overall operation and the food products you distribute are in compliance with the law.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act. Similarly, it is not necessary for you to personally ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of an animal drug that had been shipped in interstate commerce is sufficient to hold you responsible.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating the corrections have been made.

Your reply should be directed to Patricia Murphy, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mrs. Murphy at (781) 596-7758.

Sincerely,

Gail T. Costello
District Director
New England District Office

cc:

[redacted]

Vermont State Veterinary Board
Office of Professional Regulation
26 Terrace Street, Redstone Building, Drawer 09
Montpelier, VT 05609